



Transdermal Delivery: WINNING PATIENT PREFERENCE

The pharma landscape continues to be crowded and competitive, with more emphasis than ever before on delivering improved patient outcomes at a competitive price. In light of this, pharmaceutical companies must not only deliver products that effectively treat patients' problems, but also prioritize patient preference and compliance. Matching the dosage form for a product also requires a fit with your API, and each delivery method has some limitations. When drugs are designed with these factors at the forefront, they often stand out from the rest of the pack.

Let's consider the typical delivery process for a new drug product. A common mistake many pharmaceutical companies make right from the beginning is to gravitate automatically to an oral formulation. This is likely due to the fact that companies are experienced with this method, which might make it seem like there's no need to consider alternatives. Pharmaceutical companies can quickly determine if an alternative delivery form is technically feasible for a drug, by choosing the right contract manufacturing partner (CMO). For many patient conditions, this alternative to oral delivery is sorely needed. Oral delivery may actually hinder the success of a drug given the aging population and the prevalence of medical conditions that make it hard to swallow pills and keep them down. By keeping patient preference and compliance top-of-mind during the development process, companies can move into new delivery methods that better meet patients' needs. This can also improve the "outcomes vs. cost" case that must be made to global payors. If a patient is not compliant with prescribed medications, it can be costly to the payor.

What are Some Challenges with Pills?

Drug delivery via pill poses a challenge in a number of situations:

» **The elderly:** Statistics show that more than 65% of the elderly population suffers from dysphagia¹ independent of the presence of any disease or illness that could directly cause the condition. Additionally, it is esti-

ated that 25% of elderly people take at least three drugs.² As these figures show, the majority of elderly people experience some difficulty swallowing, yet often rely on a number of medications — most require swallowing — to help them manage their health conditions.

» **Patients with nausea/emesis:** Patients suffering from nausea and/or emesis clearly are not the best candidates for oral medications. Patients suffering from nausea may be able to swallow pills, but more cannot always keep them down, as they may vomit shortly after taking a pill. In this situation, patients are often left wondering if they should take another dose, or if enough time has elapsed that the original pill would be effective. For patients undergoing chemotherapy, these are recurring and long-term concerns.

» **Patients who rely on caregivers:** 40% of people who enter nursing homes do so in part because they are unable to self-medicate in their own homes, and 23% of caregivers report problems with medication management.³ Furthermore, the average nursing home patient swallows 13 pills each day.⁴ These figures present an alarming picture of the challenges facing patients and their caregivers — as the pill burden grows, both parties struggle with proper management, and administering medication becomes a problem.

This problem also occurs in additional caregiver-intensive settings such as chronic care, in which multiple medications are necessary for multiple symptoms. It can also be an issue in end-of-life care, which is now commonly taking place in patients' homes. Patients in these situations manage multiple symptoms with different medications, and their caregivers must help keep them on schedule and confirm that pills are actually swallowed.

As these examples show, there are strong opportunities for drug delivery methods outside of oral delivery in situations where patients have difficulty swallowing pills. An alternative method, transdermal delivery, offers perhaps the most patient-friendly features, as a patch can be administered painlessly and provides clear visual evidence that a dose has been given. Transdermal delivery may offer efficacy bene-

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fits as well, as this method can avoid first pass metabolism and help maintain a steady blood level of medication, as opposed to the peak and trough effect seen with many pills.

Depending on the drug's characteristics, transdermal technology has the potential to deliver a drug with a release profile of up to seven days of delivery further easing the demands placed on patients and caregivers. Another caregiver-friendly feature of a transdermal patch is the ability to have notes added with a marker. This is often done in nursing homes, where staff members write the date and time the patch was applied to provide an easy visual reference — an advantage not possible with pills. Features like this make compliance with transdermal therapy much simpler, and also help reduce the burdens placed on caregivers.

Transdermal Case Studies Tell the Story

Two transdermal products highlight the benefits of this treatment for these patient populations.

Novartis's Exelon (rivastigmine) Patch)*. Alzheimer's disease is a very caregiver-intensive condition, and a patient's ability to swallow pills can be easily compromised. The drug used in this product, rivastigmine, was initially formulated as an oral capsule. However, once the



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product was reformulated into a 24-hour Exelon Patch, the market embraced the change enthusiastically. Prescriptions for the patch increased swiftly while demand for the pill was reduced. Exelon is now the fastest growing treatment for Alzheimer's disease, and is the only transdermal patch available for the condition. By simply altering the drug delivery method, Novartis was able to improve patient compliance in addition to making the overall product more successful.

Sancuso** (Granisetron Transdermal System), marketed by ProStrakan. Granisetron has previously been available in tablet and injectable forms to treat nausea and vomiting brought on by chemotherapy treatment. However, neither of these methods was ideal given the usage scenario for the drug. The last thing patients undergoing chemotherapy want is another needle prick, and a patient experiencing nausea will also likely have problems with swallowing a pill. For patients who have received radiation treatments for head and neck cancers, there are additional problems related to damaged salivary glands and issues like oral mucositis. Geriatric patients — who represent a large portion of cancer sufferers — may also already have a compromised swallowing ability.

Recognizing these issues, ProStrakan set out to create a new type of treatment that would allow chemotherapy patients to avoid additional injections and swallowing pills. With patient preference and ease of use as top considerations, transdermal delivery quickly

emerged as the solution for this problem. The resulting product, Sancuso, can be worn for seven days. This once-weekly application is simple for both patients and caregivers, and spares patients from the daily burden of pill-taking to control emesis. Currently approved in the U.S., E.U., and South Korea, the product is also being registered in Asia, the Middle East, and Africa. ProStrakan is also exploring how the product might be used to treat nausea and vomiting related to other disorders.

Finding An Experienced Partner

As these examples show, when pharmaceutical companies truly examine the usage scenarios for a product and consider how to best match a delivery system with the patient profile, the solution is not always a pill. This realization can be daunting for companies that have little to no experience with alternative delivery systems. In these situations, working with a partner that is seasoned in development and manufacturing of transdermal systems is critical to the success of the project, and can make the development and regulatory path much easier.

In the selection process for a development and manufacturing partner, pharmaceutical companies should look for a company with a long track record of providing technical and regulatory expertise. An outsourcing partner should also demonstrate a real commitment to the partnership and the product's success. ProStrakan turned to 3M Drug Delivery Systems

for the commercial manufacturing of Sancuso, a partnership that allows the company to gain benefits of 3M's laboratory resources and international regulatory expertise. Furthermore, 3M's reliable manufacturing facilities and quality processes are laying the foundation for the expansion of Sancuso into new geographic areas.

Patient-Friendly Features Make the Difference

The examples of Exelon and Sancuso are strong illustrations of how transdermal delivery can provide a patient-friendly solution in scenarios where pills are a challenge. Pharmaceutical executives are well aware of the demographic trends the healthcare industry faces, and in light of these trends, now is the time to invest in development of solutions that will meet needs of aging patients. With painless and convenient transdermal delivery, companies can create new products that win patient preference and are easily differentiated from the competition.

Editor's Notes:

1. *Mintel: Consumer Trends 2011-2016; Glencoe Family Health Nursing Home VOC, World Journal of Pharmaceutical Research Volume 1, Issue 3, 576-590. Review Article ISSN 2277 – 7105, 2004 U.S. Bureau of the Census.* 2. *World Health Organization; World Journal of Pharmaceutical Research Volume 1, Issue 3, 576-590. Review Article ISSN 2277 – 7105.* 3. *Cost of Care- Caregiving Facts, Frontline, PBS; Palliative Care for Older People: Better Practices, WHO 2012; China Pharmaceutical Association, 2006.* 4. *3M Drug Delivery Systems Voice of Customer research. Data on file.*

*Exelon is a product and registered trademark of Novartis.

**Sancuso is a product and registered trademark of ProStrakan Group plc, manufactured by 3M Drug Delivery Systems PV

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